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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,843	06/29/2001	James P. Beck	13615.41USU1	5924

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,843

Applicant(s)

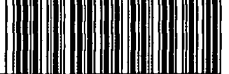
James P. Beck

Examiner

Sudhaker Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 4, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-175 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-175 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other: _____

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DETAILED ACTION

The claims in this application are the claims 1-175.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims(in part) 1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = absent; component -N = open ended i.e. not forming a closed/fused ring with N; R1 = Alkyl or (CH2)1-2-Phenyl, classified in various classes, subclass various depending on the nature and values of variables X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

II. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = absent; component -N = open ended i.e. not forming a

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closed/fused ring with N; ***R1 = other values than disclosed in Group I above,***
classified in various classes , subclasses.

- III. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component ***A = present; component -N = open ended*** i.e. not forming a closed/fused ring with N; ***R1 = Alkyl or (CH2)1-2-Phenyl,*** classified in various classes class , subclasses various depending on the nature and values of variables A, X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

- IV. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,17, drawn to ~~compounds, simple compositions, and a method of use for generic Formula (I) of~~
claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component ***A = present; component -N = open ended*** i.e. not forming a closed/fused ring with N; ***R1 = other values than in Group III above*** , classified in various classes , subclasses various depending on the nature and values of variables X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single

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species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

- V. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = absent; component -N = closed ended/fused i.e. forming a closed/fused ring with N; R1 = Alkyl or (CH2)1-2-Phenyl , classified in various classes , subclasses various depending on the nature and values of variables X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

- VI. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = absent; component -N = closed ended /fused i.e. forming a closed/fused ring with N; R1 = other values than mentioned in Group V above , classified in various classes , subclasses various depending on the nature and values of variables X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific

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single species with all variables with definite values must be disclosed.

Additionally, further restriction/election might be necessary as there are many unknowns.

- VII. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = present; component -N = closed ended/fused i.e. forming a closed/fused ring with N; R1 = Alkyl or (CH2)1-2-Phenyl , classified in various classes , subclasses various depending on the nature and values of variables A, X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

- VIII. Claims(in part)1-14,35,36-63,98,99-1203,109,110-115,122-124,128-129,132-138,146,148,150,154,158-161,162-165,166,170-171,172,174, drawn to _____ compounds, simple compositions, and a method of use for generic Formula (I) of claim 1(=A(X)(X)-N-CH(R1)-CH(OH)-C(R2)(R3)-N(R_{C-A})-(Z-Rc) wherein component A = present; component -N = closed ended/fused i.e. forming a closed/fused ring with N; R1 =other values than mentioned in Group VII above , classified in various classes , subclasses various depending on the nature and

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values of variables A,X, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

- IX. Claims(in part)15-34,35,64-98,104-109,116-121,125-127,130-131,139-145,147,151-153,155,156,157,167,173,175, drawn to compounds, simple compositions, and method of use for generic *Formula (II)* of claim 15, classified in various classes, subclasses various depending on the nature and values of variables R_N, R_{N-A}, R1, R2, R3, R_{C-A}, Z, R_C. If this group is elected a specific single species with all variables with definite values must be disclosed. Additionally, further restriction/election might be necessary as there are many unknowns.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compound, e.g. BN 80933, a NO synthase, could be used for treating the disease(s) as claimed herein.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: Formulae I and II with and without A-(X)(X)- components together with variables R₁, -N(RC-A)-Z-R_c will provide multiples of compounds with different molecules having different structures e.g. R₁ alone will provide compounds falling in U.S. classification system classes 540-548. This together with R_{N-1}-A- component, and component -N(R_{C-A})-Z-R_C also forming various heterocycles with or without substitution will further provide multiples of species which are not art recognized equivalents .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1,15,36,64,154,155,156,157,158,162,146,147,168-172-175 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. A telephone call was made to Mr. Sarussi(312 913 0001) on 9/23/02 to request an oral election to the above restriction requirement, but did not result in an election being made as the application has many claims(1-173) and multiples of possibilities of claimed compounds. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the ~~inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently~~ named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

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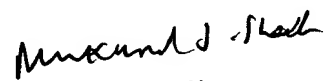
The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.



Sp/September 23, 2002.


MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1600